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09/858,366	05/16/2001	Richard A. Brauckman	TGXX-1005US	3214

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EXAMINER	
RAMANA, ANURADHA	
ART UNIT	**PAPER NUMBER**
3732	

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/858,366	Applicant(s) BRAUCKMAN ET AL.	
	Examiner Anu Ramana	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20-31 and 33-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *7-10 and 12-14* is/are allowed.

6)☒ Claim(s) *1-6,11,15-31,33 and 35* is/are rejected.

7)☒ Claim(s) *11 and 34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

In line 4 of claim 11, "house" should be "housed" to correct a minor typographical error.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 21-30 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01.

In claim 21, lines 8-11, insufficient structure is recited to support the functional language "for releasably attaching the catheter attachment to the catheter at or near the distal end of the catheter."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (US 5,302,168) in view of Dake et al. (US 5,199,939).

Hess discloses a device 10 for radiation treatment including a catheter with a balloon 36 with radioactive elements or source 38 attached to a balloon 36 wherein when the balloon 36 is expanded in the vicinity of the lesion or treatment site, the radioactive source 38 is forced into contact with the treatment site (col. 3, lines 20-45 and Figures 1, 2 and 4).

Hess also discloses an embodiment of device 10 including a retractable sheath (wire wound for radiation containment or shielding) or shield 24 that can be drawn back when the radiation source 30 in the distal end 18 of device 10 is positioned directly proximate to a

treatment site such that a window cut-out 32 in radiation source 30 is opened to expose the treatment site to a radiation dose (col. 3, lines 26-40). Further, Hess discloses an embodiment wherein the radioactive source is housed in a distal end of a catheter body 60 (Figure 6).

Hess does not disclose that the radioactive source (30, 38, 60) provides radiation in an amount from about 0.5 microcuries to about 300 microcuries per centimeter length.

Hess does not disclose that radioactive source 38 is attached to balloon 36 by bonding. The Examiner takes the position that it is well known to attach one body to the surface of another body utilizing an adhesive of sufficient bond strength to prevent subsequent separation of the bodies.

Dake et al. teach a catheter 10 for endoluminal radiation treatment having an elongated flexible, hollow body 12 with a radioactive means or "source" 14 in radioactive segment 30 of the distal section 20 of the catheter wherein the radioactive means 14 can be any shape and can be placed onto or into body 12 or manufactured into the material of body 12 and provides radiation in an amount from about 10 microcuries to about 100 curies per centimeter length of the radioactive segment 30 (Figures 1 and 9, col. 2, lines 49-54, col. 3, lines 58-68, col. 4, lines 1-8 and lines 34-36, col. 5, lines 19-22 and line 68 and col. 6, lines 1-5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source, as taught by Dake et al., to provide radiation in an amount of 0.5 microcuries to about 300 curies per centimeter length of the radioactive segment of the Hess catheter to treat restenonis since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Further, it would have been obvious to have attached the radioactive source in the device of the combination of Hess and Dake et al. by bonding to the surface of the Hess-Dake et al. catheter by utilizing an adhesive of sufficient bond strength to prevent subsequent separation of the radioactive source from the catheter body during use of the Hess-Dake et al. catheter for treatment of restenosis.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hess in view of Dake et al., further in view of Carden, Jr. (US 5,405,309).

Hess does not disclose carrier-free palladium 103 as the radiation source.

Carden, Jr. teaches carrier-free palladium 103 (Pd-103) as a safe radiation source for therapeutic purposes (col. 1, lines 40-45, col. 4 and col. 5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided carrier-free Pd-103 as the radiation source in the device of the combination of Hess and Dake et al. for enhanced safety.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess in view of Dake et al., further in view of Krasnicki et al. (US 4,676,229).

Hess discloses a device 10 for radiation treatment including a catheter with a balloon 36 with radioactive elements or source 38 attached to a balloon 36 (col. 3, lines 20-45 and Figures 1, 2 and 4) wherein when the balloon 36 is expanded in the vicinity of the lesion or treatment site, the radioactive source 38 is forced into contact with the treatment site.

Hess also discloses an embodiment of device 10 including a retractable sheath (wire wound for radiation containment or shielding) or shield 24 that can be drawn back when the radiation source 30 in the distal end 18 of device 10 is positioned directly proximate to a treatment site such that a window cut-out 32 in radiation source 30 is opened to expose the treatment site to a radiation dose (col. 3, lines 26-40).

Further, Hess discloses an embodiment wherein the radioactive source is housed in a distal end of a catheter body 60 (Figure 6).

Hess does not disclose that the radioactive source (30, 38, 60) provides radiation in an amount from about 0.5 microcuries to about 300 microcuries per centimeter length.

Hess does not disclose that radioactive source 38 is attached to balloon 36 by bonding.

Dake et al. teach a catheter 10 for endoluminal radiation treatment having an elongated flexible, hollow body 12 with a radioactive means or "source" 14 in radioactive segment 30 of the distal section 20 of the catheter wherein the radioactive means 14 can be any shape and can be placed onto or into body 12 or manufactured into the material of body 12 and provides radiation in an amount from about 10 microcuries to about 100 curies per centimeter length of the radioactive segment 30 (Figures 1 and 9, col. 2, lines 49-54, col. 3, lines 58-68, col. 4, lines 1-8 and lines 34-36, col. 5, lines 19-22 and line 68 and col. 6, lines 1-5).

Krasnicki et al. teach attachment of a body (filament) to another body (surface of a tubular substrate) using an adhesive such as epoxy cement having sufficient bond strength to hold the filament to the substrate during use (col. 3, lines 49-53).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source, as taught by Dake et al., to provide radiation in an amount of 0.5 microcuries to about 300 curies per centimeter length of the radioactive segment of the Hess catheter to treat restenonis since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Further, it would have been obvious to have attached the radioactive source in the device of the combination of Hess and Dake et al. by bonding utilizing an adhesive of sufficient bond strength, as taught by Krasnicki et al., to prevent subsequent separation of the radioactive source from the catheter body during use of the device for treatment of restenosis.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hess in view of Dake et al., and Krasnicki et al., further in view of Carden, Jr. (US 5,405,309).

Hess does not disclose carrier-free palladium 103 as the radiation source.

Carden, Jr. teaches carrier-free palladium 103 (Pd-103) as a safe radiation source for therapeutic purposes (col. 1, lines 40-45, col. 4 and col. 5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided carrier-free Pd-103 as the radiation source in the device of the combination of Hess, Dake et al. and Krasnicki et al. for enhanced safety.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie, in view of Hess, further in view of Dake et al.

Liprie discloses an elongate, flexible carrier 10 with a radioactive source 25 housed within a cavity in the distal end of carrier 10 with a plug 27 to provide access to the cavity wherein the carrier 10 is placed within conventional tubing as a protective sheath for radiation treatment of a body (Figure 1, col. 8, lines 67-68, col. 9, line 1, col. 10, lines 48-52, col. 16, lines 64-68 and col. 17, line 1).

Liprie does not disclose a retractable sheath made of radiation shielding material surrounding the flexible carrier 10.

Further, Liprie does not disclose a radiation does in an amount of about 0.5 microcuries to about 300 microcuries per centimeter length of the radioactive source.

Hess teaches a device 10 including a retractable sheath (wire wound for radiation containment or shielding) 24 that can be drawn back when the radiation source 30 in the distal end 18 of device 10 is positioned directly proximate to a treatment site such that the treatment site is exposed to a radiation does from radiation source 30 (col. 3, lines 26-40).

Dake et al. teach a catheter 10 for endoluminal radiation treatment having an elongated flexible, hollow body 12 with a radioactive means or "source" 14 in radioactive segment 30 of the distal section 20 of the catheter wherein the radioactive means 14 can be any shape and can be placed onto or into body 12 or manufactured into the material of body 12 and provides radiation in an amount from about 10 microcuries to about 100 curies per centimeter length of the radioactive segment 30 (Figures 1 and 9, col. 2, lines 49-54, col. 3, lines 58-68, col. 4, lines 1-8 and lines 34-36, col. 5, lines 19-22 and line 68 and col. 6, lines 1-5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retractable sheath in the device of Liprie for radiation containment or shielding as taught by Hess.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source 25 in the device of the combination of Liprie and Hess, to provide 10 microcuries to about 100 curies per centimeter length of source 25, as taught by Dake et al., for the purpose of treating restenosis. Further, it would have been obvious to one of ordinary skill in the art to have provided a radiation source in the device of the combination of Liprie, Hess and Dake et al. to provide radiation in an amount of 0.5 microcuries to about 300 curies per centimeter length since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over further over Liprie, in view of Hess and Dake et al., further in view of Leavitt et al.

Leavitt et al. teach a polymer depot or radioactive source wherein a radioactive material is immobilized in a polymeric material that can be in the form of a gel (col. 1, lines 49-51, col. 2, lines 39-43, col. 3, lines 44-48 and col. 4, line 52) as a source of radiation.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source within a cavity in the distal section of the body of the device of the combination of Liprie, Hess and Dake et al. wherein the radioactive source is immobilized in a polymeric material in the form of a gel as a source of radiation as taught by Leavitt et al.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie in view of Hess and Dake et al. as applied to claim 15, further in view of Carden, Jr.

See discussion for claim 6.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided carrier-free palladium-103, as taught by Carden, Jr., within a cavity in the distal section of the device of the combination of Liprie, Hess and Dake et al. for enhanced safety.

Claims 31, 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess in view of Gupta (US 5,718,684).

Hess discloses a device 10 for radiation treatment of a stenosed artery having a balloon or an expandable housing 36 with radioactive elements or source 38 attached to an outer surface of housing 36 wherein housing 36 is expanded in the vicinity of the lesion or treatment site whereby radiation source 38 is forced into contact with the treatment site (col. 3, lines 41-45 and Figures 1-4).

Hess also discloses that device 10 is provided with a mount (28, 45) for attachment to a guidewire.

Hess does not disclose that expandable housing 36 has a plurality of chambers.

Gupta teaches a multi-lobed balloon or expandable housing 30 that is mounted on and around the shaft of a catheter 25 at its distal portion 27 to prevent slippage of housing 30 in an artery with stenosis (Figures 1-3, col. 2, lines 3-40 and col. 4, lines 30-34). Further, Gupta

teaches multiple lobes or a plurality of chambers 29e, 29f, 29g and 29h that are in communication with a single flow passage 22 (col. 3, lines 40-42).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the single chamber expandable housing 36 of Hess with a multi-lobed housing, as taught by Gupta, to prevent slippage of the device of the combination of Hess and Gupta in an artery.

Allowable Subject Matter

Claims 7-10 and 12-14 are allowed.

Claim 11 would be allowable if rewritten to overcome the objection set forth in this Office action.

Claims 21-30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments see "REMARKS" section of Paper No. 12, filed on July 31, 2003, with respect to the rejections of claims 1-18, 20-31 and 33-35 have been fully considered. Accordingly, the rejections of claims 7-14 have been withdrawn. Upon further consideration, new grounds of rejection have been made with Hess as the base reference for claims 1-6, 31, 33 and 35. Hess discloses that radioactive elements 38 are attached to balloon 36 (col. 3, lines 41-45). In light of the above rejections, the Examiner asks the Attorney the question, how else can one skilled in the art, attach radioactive elements to a balloon without affecting the integrity of the balloon, if not by adhesive bonding?

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR Anuradha Ramana
October 16, 2003

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